

K063357

**510(k) SUMMARY**

JUL 10 2007

November 3, 2006

CONTACT: Douglas L. Harris  
Greiner Vacuette North America, Inc.  
4238 Capital Drive  
Monroe, NC 28110

NAME OF DEVICE:

Trade Name: Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with dipotassium EDTA (K2EDTA)  
Common Names/Descriptions: Blood Collection System  
Classification Name: Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICES:

Greiner Bio-One VACUETTE® Evacuated Blood Collection Tube with K2EDTA (K014104); Becton Dickinson Microtainer® Tube with K<sub>2</sub> EDTA (K940905)

DEVICE DESCRIPTION:

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with K2EDTA are non-evacuated, non-sterile, low sample volume tubes made from virtually unbreakable, highly transparent polypropylene. The tube measures 11 x 40 mm and there is a pre-defined nominal fill volume of 0.5 mL for achieving correct additive concentrations.

INTENDED USE:

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes are designed for the collection, transportation and processing of capillary blood (collected via lancet stick) whenever a small amount of blood is preferred.

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with dipotassium EDTA (K2EDTA) are used to obtain whole blood for testing parameters in hematology.

SUBSTANTIAL EQUIVALENCE:

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with K2EDTA are substantially equivalent to the Greiner Bio-One VACUETTE® Blood Collection Tube with K2EDTA (K014104) and the Becton Dickinson Microtainer® Tube with K2EDTA (K940905) in intended use, design and composition.

A study was conducted to demonstrate substantial equivalence of the Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with K2EDTA with the Greiner Bio-One VACUETTE® Blood Collection Tube with K2EDTA (K014104) and the Becton Dickinson Microtainer® Tube with K2EDTA (K940905) when samples from these tubes are used in hematology assays.

The conclusion from the study is that the hematology results from samples collected in the Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with dipotassium EDTA (K2EDTA) are substantially equivalent to those collected in the predicate tubes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 10 2007

Douglas L. Harris  
Greiner Vacuette North America, Inc.  
4238 Capital Drive  
Monroe, North Carolina 28110

Re: k063357

Trade/Device Name: Greiner Bio-One MiniCollect Capillary Blood Collection Tubes  
with dipotassium EDTA (K2EDTA)

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood Collection System

Regulatory Class: Class II

Product Code: JKA

Dated: June 13, 2007

Received: June 15, 2007

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

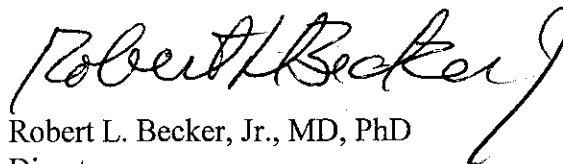
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr.", with a stylized flourish at the end.

Robert L. Becker, Jr., MD, PhD

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device Evaluation  
and Safety

Center for Devices and Radiological Health

Enclosure

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cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ- Division  
D.O.

## Indications for Use

510(k) Number (if known): K063357

Device Name: Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with dipotassium EDTA (K2EDTA)

Indications for Use:

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes are designed for the collection, transportation and processing of capillary blood (collected via lancet stick) whenever a small amount of blood is preferred.

Greiner Bio-One MiniCollect® Capillary Blood Collection Tubes with dipotassium EDTA (K2EDTA) are used to obtain whole blood for testing parameters in hematology.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

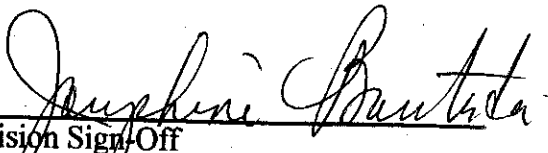
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety  
(OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K063357